

## REMARKS/ARGUMENTS

Claims 1, 2, 4, 6-10, 15, 18, 20, 21, 26, and 48-50 remain in this application. Claims 3, 11-13, 16, 22, 23, 25, 27-30, and 41-45 stand withdrawn. Claims 5, 14, 17, 19, 24, 31-40, 46, and 47 have been canceled.

### 1. Rejection of Claims 1, 2, 4, 6-10, 15, 18-20, and 48-50 Under 35 U.S.C. 102(e)

Claims 1, 2, 4, 6-10, 15, 18-20, and 48-50 stand rejected under 35 U.S.C. 102(e) as being anticipated by Michelson et al. (U.S. Patent No. 5,782,919; referred to herein as "Michelson".)

Applicants respectfully request clarification with respect to this rejection in that U.S. Patent No. 5,782,919 is issued to Zdeblick et al. rather than Michelson. Applicants believe that the Examiner is referring to U.S. Patent No. 6,890,355, issued to Michelson, as this patent is identified in the Notice of References Cited and corresponds with the discussion provided by the Examiner on page 2 of the Office Action dated February 28, 2008.

Applicants also believe that claim 19 was previously canceled. If this is incorrect, Applicants respectfully request clarification with respect to the status of claim 19.

Claim 1 calls for a vertebral body replacement comprising a body with a top, a bottom, an anterior face, a posterior face, and *two, opposing growth hole faces*, wherein *the body is asymmetric when viewed from the top* and wherein *one of the growth hole faces is a planar face and the other growth hole face is arcuate* when viewed from the top; at least one passage passing through the body from the top to the bottom; wherein at least one protrusion is formed on at least one of the top and the bottom; wherein at least one hole is provided in each growth hole face extending through the growth hole face; and wherein the top includes at least one elongated groove that extends generally along the top anteriorly-to-posteriorly and

parallel to the planar face; and wherein the bottom includes at least one groove that extends generally parallel to the planar face. (Emphasis added.)

Michelson discloses artificial contoured spinal fusion implants. However, Michelson does not disclose a vertebral body replacement with two, opposing growth hole faces, wherein the body is asymmetric when viewed from the top and wherein one of the growth hole faces is a planar face and the other growth hole face is arcuate. From column 6, line 54 to column 7, line 37 (emphasis added), Michelson discloses:

FIGS. 14-19 show an implant 300 in accordance with another preferred embodiment of the present invention adapted for use from the anterior approach to the spine. FIG. 14 shows a rear perspective view of implant 300. ***Implant 300 includes at least two members 300', 300" that are adapted to be placed side by side with one another.*** Member 300' is preferably, but need not be a mirror image of member 300". The description of member 300' is equally applicable to member 300". Member 300' has a leading portion 302' for insertion first into the disc space between two adjacent vertebral bodies and a trailing portion 304' opposite leading portion 302'. Member 300' has a top 306', a bottom 308', ***an interior side 310'***, and an exterior facing side 312' opposite interior facing side 310'. As used herein, ***the phrase "interior side" describes the side of the member adapted to be orientated toward the interior side of another member when a pair of members are inserted side by side into the disc space.***

Leading portions 302', 302" of each member 300', 300", respectively, form leading end 302 of implant 300 when the members are placed side by side to one another. Leading end 302 of implant 300 is preferably configured in the shape of one-half a first circle from side to side. Trailing end 304, composed of trailing portions 304', 304" when members 300', 300" are placed side by side to one another, may, but need not be formed as an arc of a second circle side to side having a radius greater than a radius of the first circle associated with leading end 302 of implant 300.

Member 300' is placed side by side with member 300" so that ***a portion of interior side 310' of each member are adjacent one another.*** Top 306' and bottom 308' preferably have at least one opening 314' passing therethrough between leading and trailing portions 302', 304', respectively, and sides 310', 312'. Openings 314' are adapted to hold bone growth promoting material to permit for the growth of bone from vertebral body to vertebral body through openings 314'. ***Interior side 310' may also include at least one opening 314' passing therethrough configured to permit bone growth between and into adjacent members 300', 300".*** Member 300' preferably has a maximum width W that is less than approximately one-half the width of the adjacent vertebral bodies into which the member is adapted to be inserted. Also, the combined width of both members 300', 300" is preferably greater than one-half the width

of the adjacent vertebral bodies into which the members are adapted to be inserted.

Members 300', 300" provide the added advantage in that each member can be inserted through a smaller space than a single larger implant, to achieve the same effect as the larger implant.

(Emphasis added)

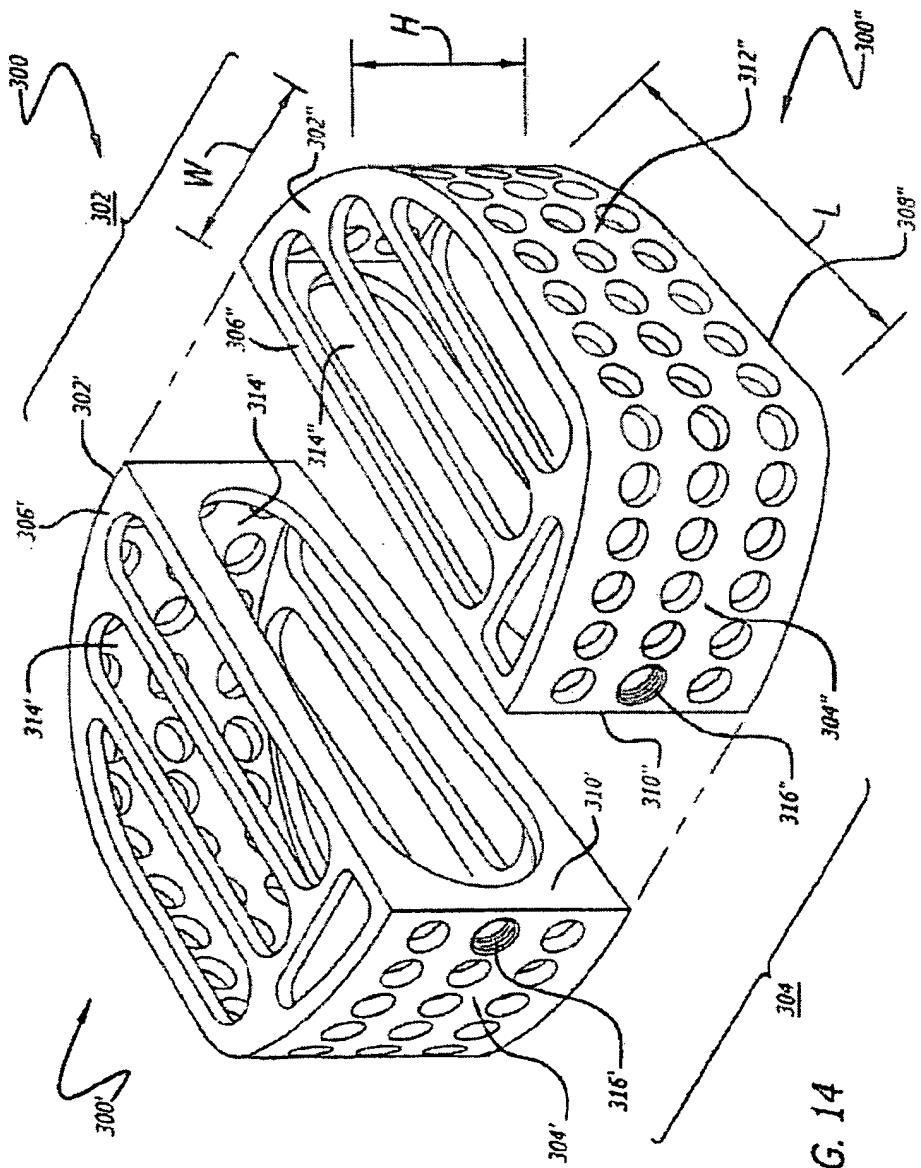


FIG. 14

Michelson discloses a vertebral body replacement member 300 which is symmetric, rather than asymmetric, when viewed from the top (see FIG. 14 above) and includes "at least two members 300', 300" "that are adapted to be placed side by side with one another." Members 300' and 300" each include interior sides 310' and 310" which are "adapted to be orientated toward the interior side of another member when a pair of members are inserted side by side into the disc space." Michelson discloses "[i]nterior side 310' may include at least one opening 314' passing therethrough configured to permit bone growth between and into adjacent members 300' and 300"." However, opening 314' is not a growth hole face, but rather a growth hole opening within a portion of the replacement member 300 as two members 300' and 300" are designed to be used with one another. In other words, opening 314' does not provide a face. In contrast to the claimed invention, members 300' and 300" each provide symmetric portions such as at side 312", which may be referred to as a face. Accordingly, claim 1 is believed to be allowable.

Claims 2, 4, 6-10, 15, 18, 20, and 48-50, which each depend either directly or ultimately from independent claim 1, are believed to be allowable for at least the same reasons identified above with respect to claim 1.

## 2. Rejection of Claim 21 Under 35 U.S.C. 103(a)

Claim 21 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson in view of Paul et al. (U.S. Patent No. 6,143,033; referred to herein as "Paul".)

Claim 21 includes the limitations of claim 1 discussed above, and further recites that the body is a section from the shaft of a femur and comprises a portion of the femur medullary cavity. Neither Michelson nor Paul teach or suggest a vertebral body replacement with two, opposing growth hole faces, wherein the body is asymmetric when viewed from the top and wherein one of the growth hole faces is a

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planar face and the other growth hole face is arcuate. Accordingly, claim 21 is believed to be allowable.

### 3. Rejection of Claim 26 Under 35 U.S.C. 103(a)

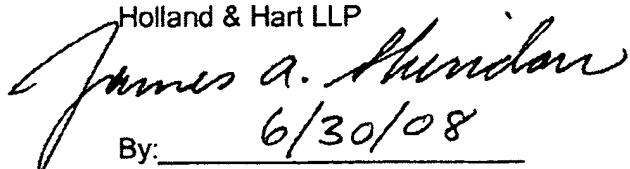
Claim 26 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson in view of Wagner et al. (U.S. Patent No. 5,306,309; referred to herein as "Wagner".)

Claim 26 includes the limitations of claim 1 discussed above, and further recites that the body comprises a plurality of bonded layers. Neither Michelson nor Wagner teach or suggest a vertebral body replacement with two, opposing growth hole faces, wherein the body is asymmetric when viewed from the top and wherein one of the growth hole faces is a planar face and the other growth hole face is arcuate. Accordingly, claim 26 is believed to be allowable.

### Conclusion

In light of the amendments and remarks provided herein, Applicant respectfully requests the timely issuance of a Notice of Allowance.

Respectfully submitted,  
Holland & Hart LLP



By: \_\_\_\_\_  
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